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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/493,480	01/28/2000	Martin A. Cheever	0140580-009810	2303

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EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1642	22

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/493,480	CHEEVER ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *93-130* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *93,97-103,107-118,121,122 and 124-130* is/are rejected.

7)☒ Claim(s) *94-96,104-106,119,120 and 123* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *21* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 9, 2003 has been entered.

2. Claims 93-130 are pending and examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 93, 97-103, 107-116, 121, and 124-130 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The basis for this rejection is two-fold: the genus of fusion proteins defined by the hybridization conditions of the coding sequences is not described in the specification,

either explicitly or implicitly, and the genus of claimed fusion proteins is not described, because the structures provided are not representative of the claimed genus.

The original claims were drawn to nucleic acids encoding fusion proteins having at least 80% sequence identity to reference protein sequences. The amendment filed April 25, 2001 (Paper No. 10) fails to point to support in the specification for the claimed genus of nucleic acids. While the specification contains descriptions of hybridization conditions and definitions of conditions that correspond to various levels of stringency, nowhere in the specification is there support for a genus of nucleic acids encoding fusion proteins where the genus of nucleic acids is defined by their ability to reference sequences under the conditions recited in the claims.

The claimed inventions are also rejected under 35 U.S.C. 112, first paragraph, because the specification lacks written description of the full scope of the claimed genus; the nucleic acids encoding the exemplary fusion proteins are not representative of the claimed genus. For a genus of products to be adequately described, the specification must provide at least the structural features common to the members of the genus. This may be done by describing a representative number of species of the genus, or by providing partial structures, physical or chemical characteristics, or functional characteristics coupled with a known or disclosed correlation between structure and function. In the instant case, the claims are drawn to nucleic acids that may hybridize to the complement of nucleic acids that encode either SEQ ID NO: 6, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 7 or SEQ ID NO: 5. SEQ ID NO: 6 is a fusion protein of a human Her-2 extracellular domain and a human Her-2 phosphorylation domain. SEQ ID NO: 7 is a fusion protein of a human Her-2 extracellular domain and a fragment of a

human Her-2 phosphorylation domain. SEQ ID NO: 3 is a human Her-2 extracellular domain. SEQ ID NO: 4 is a human Her-2 phosphorylation domain. SEQ ID NO: 5 is a fragment of a human Her-2 phosphorylation domain. The specification fails to teach the critical features of these sequences that must be included to make a fusion protein that falls within the scope of the claims. As the claims currently read, the claimed nucleic acids encode fusion proteins that encompass structures that have high similarity to one domain of the fusion protein, fused to, perhaps, only one amino acid from the other domain. The specification lacks a definition of the scope of a Her-2 extracellular domain and also the scope of a Her-2 phosphorylation domain; specifically the specification fails to teach how much of the extracellular or phosphorylation domain may be missing and still be defined as such. Furthermore, the definition of the human and rat extracellular domains and phosphorylation domains is not a definition of all Her-2 extracellular domains or all Her-2 phosphorylation domains.

Applicant has pointed to language in the broad claims that is purported to be "functional characteristics" of the claimed fusion proteins; specifically that the claimed fusion proteins induce an immune response in a warm blooded animal. This functional characteristic is so broad that it may apply to almost any protein. Therefore, the functional language fails to add the requisite disclosure of a correlation between structure and function of the proteins encoded by the claimed nucleic acids.

Because the claims introduce new matter into the specification and because the genus of claimed fusion proteins are not described, it does not appear that applicant was in possession of the claimed inventions at the time application was filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 93, 97-103, 107-112, 117, 118 and 122 are rejected under 35 U.S.C. 102(e) as being anticipated by Kipps (U.S. Patent 6,287,569; issued Sep. 11, 2001; effective filing date Apr. 10, 1997).

The claimed inventions are drawn to nucleic acids encoding fusion proteins comprising a Her-2/neu extracellular domain fused to a Her-2/neu phosphorylation domain, where the nucleic acid hybridizes under stringent conditions to the complement of a nucleic acid encoding he amino acid sequence of SEQ ID NO: 6 or to SEQ ID NO: 7, and separately to SEQ ID NO: 3 and separately to SEQ ID NO: 4 or to SEQ ID NO: 5. The nucleic acids may comprise sequence that encodes an amino acid linker, may be part of a viral vector, or a composition further comprising a physiologically acceptable carrier or diluent, or further comprising an immunostimulatory substance. The composition may be a vaccine and the nucleic acid may be a DNA molecule.

Kipps discloses a vector comprising a nucleotide sequence encodes a chimeric immunogen that comprises the ErbB-2 (Her-2/neu) tumor antigen (see claim 1; col. 3, line 3 to col. 5, line 10). Kipps also teaches the addition of adjuvants (see col. 7, lines 26-

32). Because ErbB-2 comprises the extracellular domain and the phosphorylation domain it reads on a fusion protein with an amino acid linker. Therefore, Kipps teaches nucleic acids and compositions as claimed.

6. Claims 93, 97, 102, 103, 107, 112, 113, 117, and 118 are rejected under 35 U.S.C. 102(e) as being anticipated by Hudziak (U.S. Patent 6,015,567; issued Jan. 18, 2000; effective filing date May 19, 1989; cited in the IDS).

Hudziak teaches a nucleic acid encoding a fusion protein that comprises an extracellular domain of a human Her-2 fused to an intracellular portion of a human Her-2, and lacks a transmembrane domain (see Figure 1B, $p185^{HER2\Delta TM}$; col. 3, lines 9-11). Hudziak teaches methods of making fusion proteins. Thus, Hudziak teaches nucleic acids and methods that are the same as that claimed.

7. Claims 93, 99-101, 103, 109-111, and 125-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipps (supra) in view of Carrano (U.S. Patent 5,962,428; issued Oct. 5, 1999; effective filing date Sep. 16, 1996).

The claimed inventions include within their scope nucleic acids that are comprised within vaccine preparations further comprising immunostimulatory substances such as 3D-MPL or QS21, or compositions comprising an oil-in-water emulsions or tocopherol.

Kipps generally teaches vaccine compositions further comprising immunostimulatory substances, but fails to teach specifically such substances as 3D-MPL or QS21, or compositions comprising oil-in-water emulsions or tocopherol. However,

Carrano teaches methods for enhancing nucleotide vaccines and teaches MPL, QS21, oil-in-water emulsions and tocopherol (see col. 3, lines 13-28; col. 15, line 55 – col. 16, line 26; col. 19, lines 44-60). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the vaccine compositions of Kipps by adding the adjuvant compositions of Carrano.

8. Claims 93, 99-101, 103, 109-111, and 130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipps (supra) in view of Krieg (U.S. Patent 6,429,199; issued Aug. 6, 2002; filing date Nov. 13, 1998).

The claimed inventions include within their scope nucleic acids that are comprised within vaccine compositions comprising a CpG-containing oligonucleotide.

Kipps generally teaches vaccine compositions further comprising immunostimulatory substances, but fails to teach specifically such substances as a CpG containing oligonucleotide. However, Krieg teaches the benefits of including CpG oligonucleotides in vaccine compositions and teaches that CpG oligonucleotides are useful for activating dendritic cells (col. 3, line 66 – col. 4, line 14). Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have included CpG containing oligonucleotides in the nucleic acid vaccine compositions of Kipps.

Conclusion

No claim is allowed. Claims 94-96, 104-106, 119, 120, 123 are objected to for depending on rejected claims. Claims 93, 97-103, 107-118, 121, 122, 124-130 are rejected.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
October 26, 2003

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